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5. 510(k) Summary

The summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

The assigned 510(k) number is K101371

Submitters Identification:

ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego, California 92121

Tel: 858-875-8019
Fax: 858-875-8099

Date prepared: May 7th, 2010

Contact Person:

Richard Lenart
Regulatory Affairs Manager

Proprietary Name of the Device:

On Call® Plus Diabetes Monitoring Software

Common name:

Diabetes Software

Classification Name:

Class I §862.2100 Calculator/data processing module for clinical use.
Class II §862.1345 Glucose Test System
(To be manufactured and marketed for consumer home and professional use)

Predicate Device:

Glucofacts® Deluxe Diabetes Management Systems
Bayer Healthcare
430 South Beiger Street, Mishawaka, IN 46544
510(k) K091820

Device name: On Call® Plus Diabetes Monitoring Software

Proprietary Name	Classification	Product Code	Description	Common Name
On Call® Plus Diabetes Monitoring Software	§862.1345 §862.2100	NBW, JQP	System, Test, Blood Glucose, Over The Counter	Diabetes Software

Description:

The On Call® Plus Diabetes Monitoring Software is for downloading glucose data from the On Call Plus meter to a PC through an USB to RS232 TTL level cable or RS232 to RS232 TTL level cable, with tracking and trending capabilities of glucose measurements.

The Diabetes Data Management Software is intended to be used in a clinical setting with multiple patients by a healthcare professional, or directly by the patient.

The user has the choice to install either a personal "Home" or "Professional" version. In the "Home" version, glucose results are assembled for a single user. In the "Professional" version, the software user can configure a database with multiple providers and patients, The number of providers, patients and data points is limited only by the computer's capabilities.

Intended Use:

The On Call® Plus Diabetes Software is an optional software accessory to be used with the On Call® Plus Glucose Meters for transferring data to a computer and organizing it in tables and graphs to be used at home and by health care professionals. The software does not recommend any medical treatment or medication dosage level.

Technological Characteristics:

Feature	Specification
System Requirements	Pentium or equivalent processor, USB or RS-232 9-pin serial port, 128 MB memory, 70 MB hard drive space, minimum 800 x 600 display, CD-ROM drive
Operating Systems	Microsoft Windows 2000, XP Home/Professional, Vista, windows 7
Reports, Charts and Graphs	Data list report, line, bar and pie charts, average day line chart, average day/week bar charts,
Glucose Units of Measure	millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL)
Users	Multiple users and patients limited only by the capabilities of the computer being used
Passwords	Create databases that are password protected

Delete Memory	Can delete patients, providers, databases and data stored in meters

Comparison to Predicate Device:
The On Call® Plus Diabetes monitoring Software is substantially equivalent to Glucofacts® Deluxe Diabetes Management Software (K091820)

Features	On Call® Plus Diabetes Monitoring Software	Glucofacts® Deluxe Diabetes Management Software (K091820)
Similarities		
COM Ports scan	Automatic scan for connected ports	Same
Multiple patients	Can list data for multiple patients	Same
Data list/ Summary report	List of all readings inside selected time frame	Same
Reports and charts	Data List, Log Book report, Standard Day report, Trend report, Pie charts	Same
Target levels	High, low, hyper and hypo glucose target levels can be changed	Same
Time periods	Daily time periods can be changed	Same
Units of measure	Can choose either mmol/L or mg/dL	Same
Data Base	Can Set up multiple patient data bases	Same
Differences		
Change Meter settings	Does not allow change to meter settings through the Diabetes Monitoring Software	Allows target range, alarm sounds and optional level changes to supported meters through the Management Software
Operating System	Microsoft Windows 2000, XP Home/Professional, Vista, windows 7	Microsoft Windows XP, Vista or Mac OS 10.5.7 or later (Mac is only an option with the Contour USB meter)
Associate a meter to a person	No association	Software can be set to recognize meters and associate them to specific patients
Standard week report	No Standard Week report	A graph that displays all readings by day overlapping all the days on a one week graph
Average Week	A bar graph that averages all readings for each day by day of the week, Sunday through Saturday and before and after meals.	No average week report
Average Day	A bar graph that averages all readings for each day by time slot and before and after meals.	No average day report
Password	Allows providers accounts to be password protected	Does not have password protection on the software
Providers	Allows for multiple providers each with their own data base of patients	Does not have providers but does allow for multiple databases

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:

The performance characteristics of the On Call® Plus Diabetes Monitoring Software were evaluated by performing the software validation test. Guidance documents included "Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff." Compliance to applicable voluntary standards includes EN 62366:2008, "Medical devices, Application of usability engineering to medical devices" and EN 62304:2006 "Medical device software, Software life cycle processes."

Discussion of Clinical Tests Performed:

Clinical studies were conducted with lay persons using the On Call® Plus Diabetes Monitoring Software to demonstrate that the intended user can easily operate the software features including Installing the software, transferring meter data to the computer, changing settings, setting up providers and patients, using passwords, viewing and printing reports and uninstalling the software.

Study results indicate that non-professional, inexperienced lay persons were able to operate the software and obtain glucose trending reports. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the User's Manual and the overall performance of the On Call® Plus Diabetes Monitoring Software.

Conclusion:

The laboratory testing and clinical study results demonstrate that the On Call® Plus Diabetes Monitoring Software is safe, effective and easy-to-use. It demonstrates that the On Call® Plus Diabetes Monitoring Software meets all the validation and clinical requirements and is substantially equivalent to the Bayer Glucofacts Deluxe Diabetes Management Software sold on the U.S. market (K091820).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JAN 07 2011

Acon Laboratories, Inc.
c/o Richard Lenart
10125 Mesa Rim Rd.,
San Diego, CA 92121

Re: k101371
Trade/Device Name: On Call Plus Diabetes Monitoring Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: December 3, 2010
Received: December, 6, 2010

Dear: Mr. Lenart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) number (if known): k101371

JAN - 7 2011

Device Name: On Call® Plus Diabetes Monitoring Software

Indications for Use:

The On Call® Plus Diabetes Software is an optional software accessory to be used with the On Call® Plus Glucose Meter for transferring data to a computer and organizing it in tables and graphs to be used at home and by health care professionals. The software does not recommend any medical treatment or medication dosage level.

Prescription Use_____ AND/OR Over-The-Counter Use__X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k101371